IX. 510(k) Summary

SUBMITTER:	DePuy AcroMed™, Inc. 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Karen F. Jurczak
DATE PREPARED:	April 28, 2000
CLASSIFICATION NAME:	Implant, fixation device Spinal Interlaminal Fixation Orthosis Pedicle Screw Spinal System
PROPRIETARY NAME:	E-Z Link Cross Connector
PREDICATE DEVICES:	AcroMed Cross Connector (K874882) MOSS Miami Transverse Connector (K955348)
INTENDED USE:	The ISOLA Posterior Spinal System, when used with pedicle screws, is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine. The ISOLA Spinal System is also indicated for pedicle screw fixation for severe Grade 3 and 4 spondylolisthesis at L5-S1, in skeletally mature patients, utilizing autologous bone graft, having the device fixed or attached to the lumbar or sacral spine and intended to be removed after solid fusion is attained. Levels of attachment for this indication range from L3 to the sacrum. The ISOLA Spinal System, when not used with pedicle screws, is intended for hook, wire, and/or sacral/iliac screw fixation from T1 to the ilium/sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture, and previous failed fusion.

MATERIALS:	Manufactured from ASTM F-138 implant grade stainless steel or ASTM F-136 implant grade titanium alloy.
PERFORMANCE DATA:	Biomechanical testing, including static cantilever beam testing, static axial slippage, static torsion, and cantilever beam fatigue, were conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2000

Mr. Frank Maas
Regulatory Affairs Manager
DePuy Acromed
A Johnson & Johnson Company
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K001372/A1
Trade Name: E-Z Link Cross Connector
Regulatory Class: II
Product Codes: KWP, KWQ, MNH and MNI
Dated: May 10, 2000
Received: May 11, 2000

Dear Mr. Maas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bachner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications for Use

510(k) Number (if known): K001372

Device Name: E-Z Link Cross Connector

Indications For Use:

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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use:
(Per 21 CFR 801.109)

Donna R. Lachman
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001372